IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

OUTSOURCING FACILITIES ASSOCIATION, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Civil Action No. 4:24-cv-00953-P

Plaintiffs' Motion for Summary Judgment

Plaintiffs Outsourcing Facilities Association and North American Custom Laboratories, LLC, doing business as FarmaKeio Custom Compounding, by and through undersigned counsel, and pursuant to Rule 56 of the Federal Rules of Civil Procedure and LR 56.1–56.7, respectfully move for summary judgment on all claims within their Amended Complaint (ECF No. 68):

Summary

FIRST CAUSE OF ACTION – That FDA's decision declaring an end to the tirzepatide shortage (the Delisting Action) is final agency action for which there is no other adequate remedy; that the Delisting Action is a legislative rule that imposes prospective prohibitions on an entire industry; that the Delisting Action is subject to the requirement of notice-and-comment rulemaking under the Administrative Procedure Act (APA); and that FDA did not promulgate the Delisting Action through notice-and-comment rulemaking.

SECOND CAUSE OF ACTION – That the Delisting Action is final agency action for which there is no other adequate remedy; and that FDA issued the Delisting Action without findings on critical statutory elements FDA claimed to analyze, such as the time period subject to

analysis and the supply and demand for that time period or reasons for choosing one time period over another.

THIRD CAUSE OF ACTION – That the Delisting Action is final agency action for which there is no other adequate remedy; and that FDA issued the Delisting Action based on findings that are internally contradictory and unsupported by substantial evidence.

FOURTH CAUSE OF ACTION – That the Delisting Action is final agency action for which there is no other adequate remedy; and that FDA issued the Delisting Action based on findings in contradiction to the weight of evidence showing that a shortage persists.

FIFTH CAUSE OF ACTION – That the Delisting Action is final agency action for which there is no other adequate remedy; and that FDA issued the Delisting Action based on flawed legal premises.

SIXTH CAUSE OF ACTION – That the Delisting Action is final agency action for which there is no other adequate remedy; that the APA requires that actions like the Delisting Action be published in the Federal Register; and that FDA failed to publish the Delisting Action in the Federal Register.

The elements of each claim as to which summary judgment is sought are fully articulated in Plaintiff's Memorandum in Support of Motion for Summary Judgment, which will be filed in accordance with LR 56.5, and comply with the requirements of LR 7.2. In accordance with LR 56.6, Plaintiffs will also file an Appendix.

Requested Relief

Plaintiffs respectfully ask the Court to enter an order granting this Motion for Summary Judgment, and request the following relief against Defendants:

1. Issue a declaratory judgment that the Delisting Action is arbitrary, capricious, and/or otherwise contrary to law;

2. Set aside and/or vacate the Delisting Action;

3. Remand to FDA to reassess issues relevant to the Delisting Action in a manner consistent with the Court's opinion;

4. Permanently enjoin FDA from taking action predicated on the Delisting Action; and

5. Grant Plaintiff such other relief as may be necessary or appropriate or that the Court deems just and proper.

Respectfully submitted this the 2nd day of April, 2025.

/s/ Ty Doyle

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Certificate of Service

I hereby certify that this document, filed through the CM/ECF system on this day, will be sent via electronic mail to the registered participants as identified on the Notice of Electronic Filing

Dated: April 2, 2025

/s/ Ty Doyle

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